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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,414	04/03/2001	Alan Collmer	19603/3243 (CRF D-2601C)	2043
7590 02/09/2004			EXAMINER	
Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 02/09/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/825,414	<b>Applicant(s)</b> COLLMER ET AL.	
	<b>Examiner</b> Robert A. Wax	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 38-45 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 38-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11032003</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Upon reconsideration of applicants' arguments regarding the similarity of SEQ ID No. 7 and SEQ ID No. 66, the restriction requirement between them is hereby withdrawn. This Office action reflects the findings of a search of SEQ ID No. 66.

Upon reconsideration of the previous rejections, they are hereby withdrawn in favor of the new rejections below.

### ***Information Disclosure Statement***

2. The information disclosure statement filed November 3, 2003 has been considered. Please see the attached initialed PTO-1449.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 7-9 and 38-45 are rejected under 35 U.S.C. 102(b) as being anticipated by AAF71504 (Submitted 07-FEB-2000; Alfano and Collmer, Dept. Biol. Sci, UNLV, 1854 Maryland Parkway, Las Vegas, NV 89154, USA), hereinafter styled Alfano et al.

Alfano et al. teach an isolated peptide having the amino acid sequence of SEQ ID No: 7. This anticipates claims 7, 8, 39, 40 and 44 with no further explanation required. Claim 9 is anticipated because the protein does not exist in a vacuum, but rather, in solution. The water is the carrier. Claim 38 is anticipated because a protein is a protein whether it is produced recombinantly or not, that is, patentability of a product is independent of the process by which it is made. Claims 41-43 and 45 are anticipated because the DNA encoding SEQ ID No. 7 must have a complement that hybridizes under the specified conditions to SEQ ID No. 6.

Applicants have argued that Alfano et al. was not published more than one year before their priority date and a declaration under 37 CFR 1.132 is submitted in support thereof. Examiner respectfully points out that the date for which a year's grace period begins under 35 USC 102 (b) is the actual filing date. The priority date may be as much as a year prior to the actual filing date but no more. A reference published even one day before the priority date qualifies as prior art under 35 USC 102(b).

Sequences are published in GenBank within two working days after submission, unless the submitter requests otherwise. The following information about submitting sequence data to GenBank is from their website (<http://www.ncbi.nlm.nih.gov/Genbank/index.html>).

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**Submitting Sequence Data to GenBank:** Most journals now expect that DNA and amino acid sequences that appear in articles will be submitted to a sequence database before publication. Soon after submission, you will receive an accession number from the database which you will be able to use in your article to refer to the sequence. Please be aware that it is only necessary to submit the sequence to one database, whichever one is most convenient, without regard for where the sequence may be published. Data exchange between GenBank, EMBL and DDBJ occurs daily. Sequence data submitted in advance of publication can be kept confidential if requested.

Below are described various ways of submitting DNA sequences to GenBank. Essentially, there are two principal ways, BankIt and Sequin. BankIt is a Web submission tool and recommended for simple submissions. With BankIt you can indicate coding regions on an mRNA along with a product and gene name. For more control over annotating your entry, segmented records, or very long entries, Sequin, a stand-alone submission tool, is suggested. GenBank will provide you with an accession number to identify your sequence, usually within two working days, if the submission is received via electronic mail. This accession number serves as confirmation that you have submitted your data, and allows the community to retrieve the data upon reading the journal article.

Therefore, since the sequence was submitted to GenBank on February 7, 2000, the reference is prior to the priority date and qualifies as prior art under 35 USC 102(b).

5. Claims 7-9 and 38-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Charkowski et al. (Ref. 2 on the 1449 filed February 4, 2002).

Charkowski et al. teach an isolated protein having the amino acid sequence of SEQ ID No: 7. This anticipates claims 7, 8, 39, 40 and 44 with no further explanation required. Claim 9 is anticipated because the protein does not exist in a vacuum, but rather, in solution. The water is the carrier. Claim 38 is anticipated because a protein is a protein whether it is produced recombinantly or not, that is, patentability of a product is independent of the process by which it is made. Claims 41-43 and 45 are anticipated



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because the DNA encoding SEQ ID No. 7 must have a complement that hybridizes under the specified conditions to SEQ ID No. 6.

The Charkowski et al. reference came up in the sequence search for SEQ ID No. 66, it shows that SEQ ID No. 66 is 77.7% identical to SEQ ID No. 7. DNA having SEQ ID NO. 65 would be expected to hybridize to DNA encoding SEQ ID No. 7 under the hybridization conditions specified in claims 7, 41, 42 and 45. Thus, this teaching anticipates claims 7, 9, 38-42 and 45 for the same reasons as above.

One of ordinary skill would not, however, expect that DNA having SEQ ID NO. 65 would hybridize to DNA encoding SEQ ID No. 7 under the hybridization conditions specified in claim 43; in fact, no such DNA was discovered during the sequence search.

### ***Conclusion***

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, from 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'R. Wax', with a stylized flourish at the end.

Robert A. Wax  
Primary Examiner  
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